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ASSOCIATE VICE PRESIDENT
US REGULATORY AFFAIRS

PhRMA

November 16, 2000

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 92N-0297; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administration Procedures; Public Hearing; 65 Federal Register 56480

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is submitting this set of comments on certain aspects of the Prescription Drug Marketing Act of 1987 (PDMA) to augment those presented at the public hearing that was held on October 27, 2000. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA member companies are devoted to inventing medicines that allow patients to lead longer, happier, healthier, and more productive lives; our members invest over $26 billion annually in the discovery and development of new medicines.

Two questions were posed to PhRMA during the discussion session following my presentation:

1. *What percentage of pharmaceuticals are sold by PhRMA member companies to secondary wholesalers that are not the authorized distributor?*

2. *Why are pharmaceutical companies reluctant to increase the number of authorized distributor?*

Unfortunately PhRMA cannot provide the FDA with answers to these questions. Both questions deal with marketing decisions made by individual PhRMA member companies, and PhRMA does not become involved in such competitively sensitive subjects.

Another issue raised concerns PhRMA's position on H.R. 4301. Consultation with PhRMA staff indicated that PhRMA opposed relaxation of the pedigree requirements. That legislative proposal would substantively change the existing requirement in §503(e)(1) that unauthorized distributors provide a pedigree (information identifying

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each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction), and instead require only that unauthorized distributors provide a "statement that the drug was first purchased from or through an authorized distributor." PhRMA opposes any such change to this PDMA requirement, because it would effectively gut the requirement that unauthorized distributors provide a pedigree for the medicines they wish to move in commerce. The drug pedigree is the only legal and reliable way of tracing the pharmaceutical back to the original manufacturer. A mere "statement" asserting that the chain of custody actually traces back to an authorized distributor is no substitute for the existing statutory pedigree information. Such a "statement" would be of little value in the event of a recall, for example, and the ease of making such a statement would foster abuse and corner-cutting.

With the passage of the "Medicine Equity and Drug Safety Act of 2000," section 745 of the FY 2001 Agriculture Appropriations bill (Public Law 106-387), that relaxes certain provisions of the PDMA governing reimportation, pedigree requirements may become increasingly important in protecting the public health. This is certainly not the time to dismantle domestic regulatory safeguards that today give FDA, pharmacies, and ultimately patients, confidence that their medicines are safe, have been properly stored, and are not counterfeit.

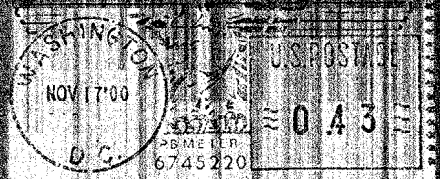
Finally, it was apparent from the hearing that all of the information relevant under FDA's final rule (21 CFR 203.50(a)(1-7)) is contained in the bill of sale from the pharmaceutical manufacturer to the wholesaler (whether authorized or not). Thus, the information can be readily incorporated either as the original bill of sale or into an appropriate form to provide pedigree information. While PhRMA can appreciate the difficulties faced by many secondary wholesalers in handling multiple pedigrees for the same pharmaceutical product, the pedigree requirement must be kept. American patients rely on their prescription drugs to provide effective medical treatment. The PDMA addressed specific safety problems with the pharmaceutical supply chain and should not be weakened. The repeal or amendment of the §503(e)(1) chain-of-custody requirement would seriously threaten to bring back the substantial public health risks that PDMA was designed to alleviate.

PhRMA wishes to again thank the FDA for the opportunity to testify at the hearing and hopes that this amplification on our earlier remarks is useful.

Sincerely,

Alan Goldhammer

PhRMA



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